Figure 1: Overall process – Flow Diagram

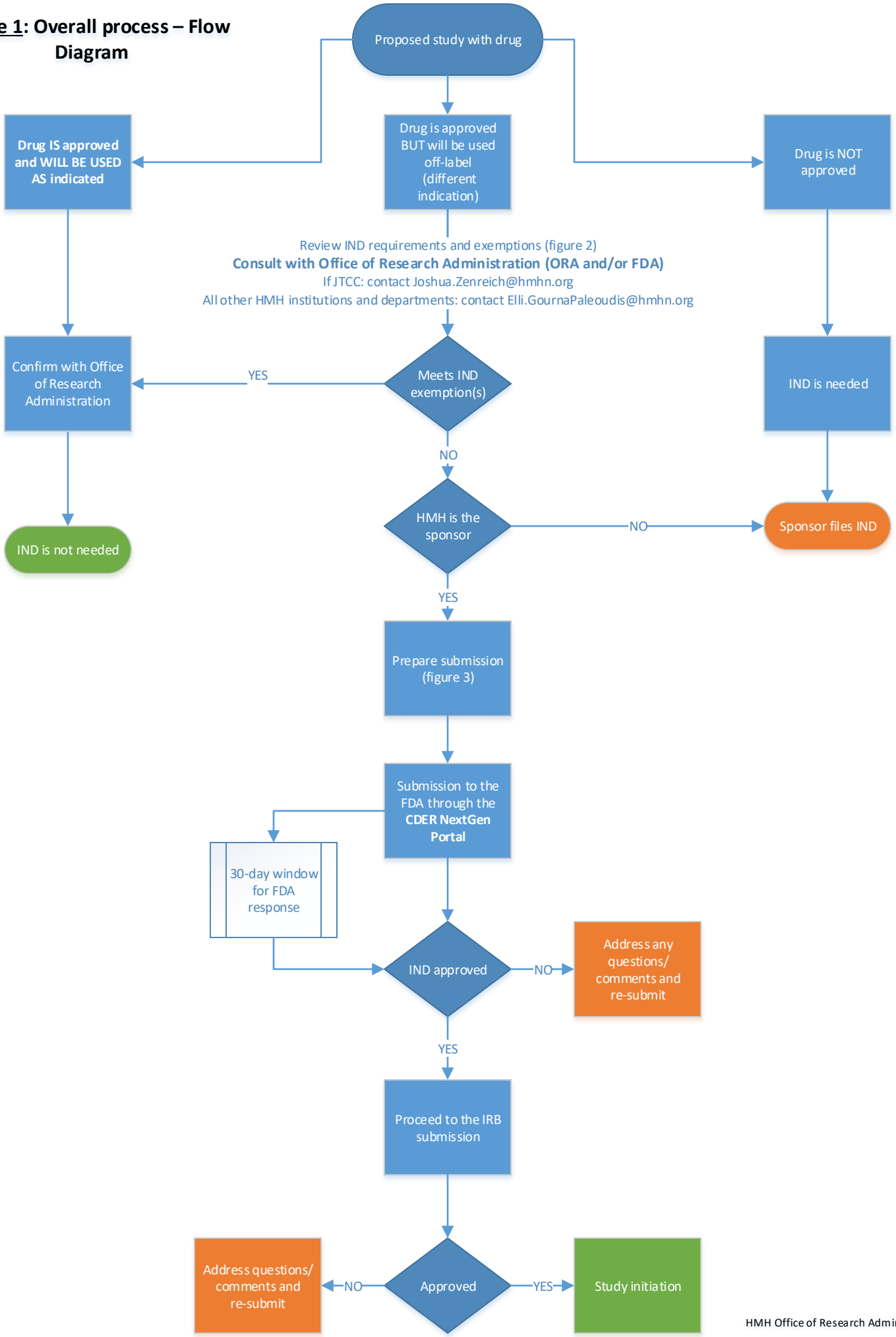
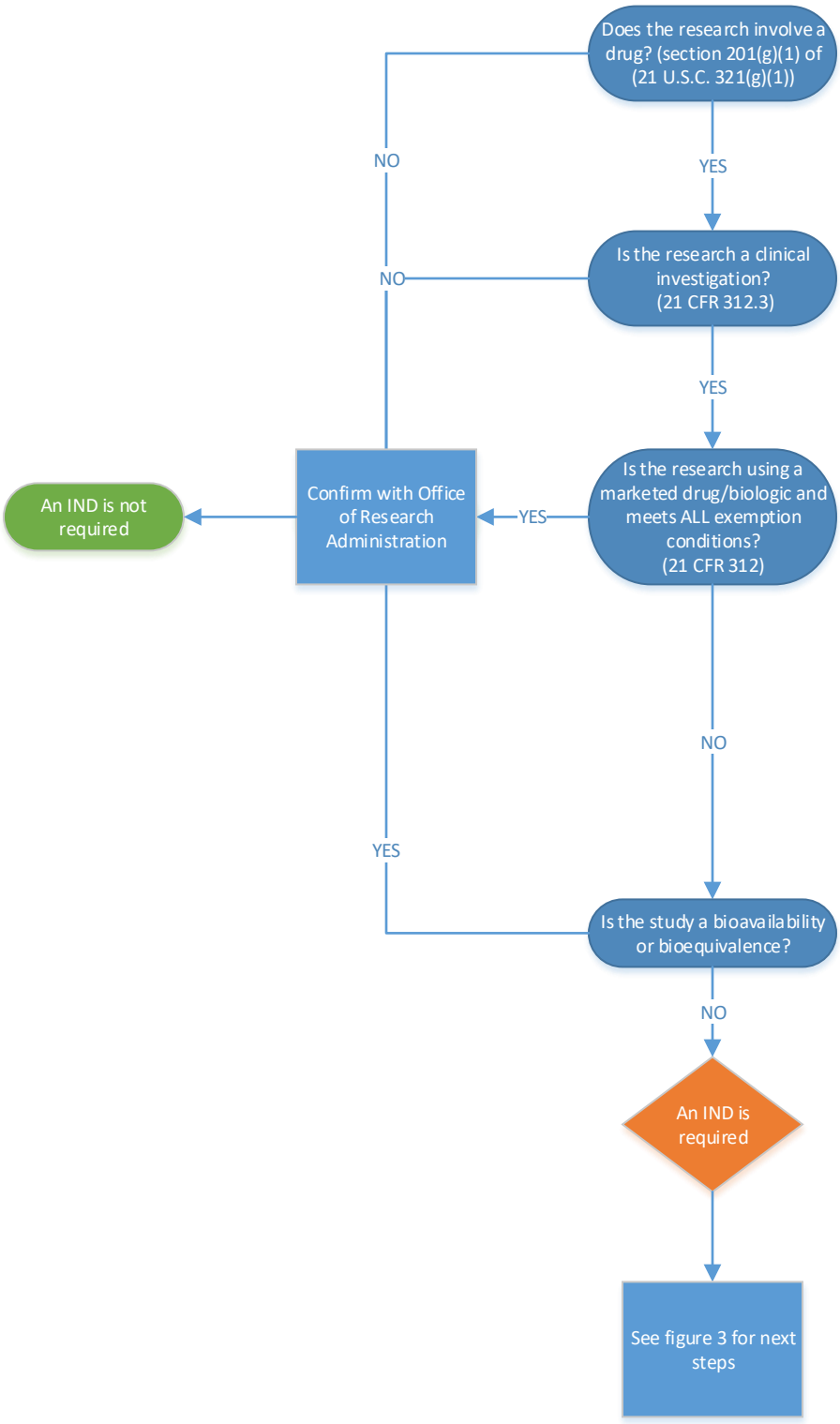


Figure 2: IND Decision Tree



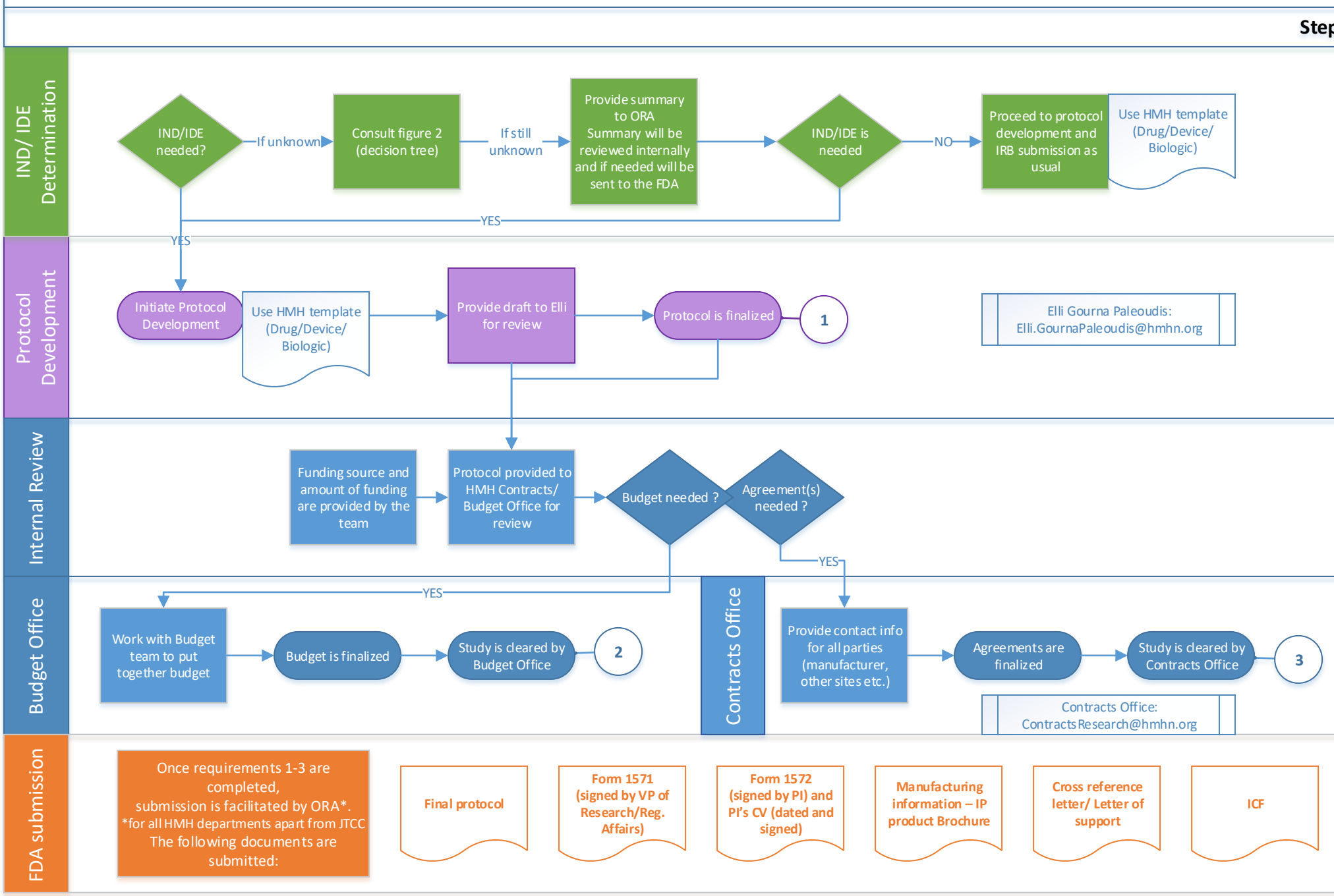
"articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." and "articles (other than food) intended to affect the structure or any function of the body of man or other animals."

"[an] experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of [the IND regulations], an experiment is any use of a drug [whether approved or unapproved] except for the use of a marketed drug in the course of medical practice."

- Investigation is not intended to support of a new indication or significant change in the labeling of the drug.
- Investigation is not intended to support a significant change in the advertising for the drug.
- Investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk associated.
- Investigation is conducted in compliance with the requirements for review by an IRB and informed consent.
- Investigation is not intended to promote or commercialize the drug product.

Bioavailability or bioequivalence studies using unapproved versions of approved drug products (21 CFR 320.31(b) and (d)).

Figure 3: Step-by-step process for Investigator Initiated Research IND



IRB submission will take place once FDA approval/ exemption has been received

HMH Office of Research Administration